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FILE: UTSC:484USC1

January 18, 2002

Commissioner for Patents  
Washington, DC 20231

RE: *U.S. Patent Application 09/943,984, Entitled: SENSITIZATION OF HER-2/NEU OVEREXPRESSING CANCER CELLS TO CHEMOTHERAPY by Mien-Chie Hung and Naoto Ueno (Ref. MDA96-012CON1)*

Sir:

Enclosed for filing in the above-referenced patent application is an Information Disclosure Statement, Form PTO-1449, and reference A7.

No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to the enclosed materials, the Commissioner is hereby authorized to deduct said fees from Fulbright & Jaworski Deposit Account No.: 50-1212/10105728/TMB.

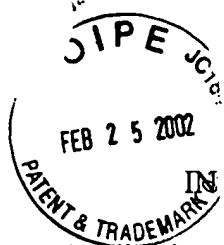
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Respectfully submitted,

*Thomas M. Boyce*  
Thomas M. Boyce  
Reg. No. 43,508

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Encl: as noted



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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Mien-Chie Hung and Naoto Ueno

Serial No.: 09/943,984

Filed: August 31, 2001

For: SENSITIZATION OF HER-2/NEU  
OVEREXPRESSING CANCER CELLS  
TO CHEMOTHERAPY

Group Art Unit: 1632

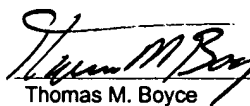
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Date	Thomas M. Boyce

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

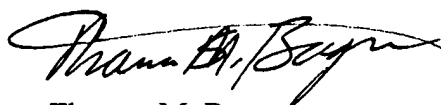
In accordance with 37 C.F.R §§ 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is hereby authorized to deduct said fees from Fulbright & Jaworski Deposit Account No.: 50-1212/10105723/TMB.

This application is a continuation application of Serial No. 08/809,021, filed March 19, 1997 and is relied upon for an earlier filing date under 35 U.S.C. § 120. In accordance with Rule 37 C.F.R. § 1.98(d) only copies of those documents not previously cited and submitted to the Patent and Trademark Office in prior application Serial No. 08/809,021 are enclosed for the convenience of the Examiner.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,



Thomas M. Boyce  
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Attorney for Applicants

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Form PTO-1449 (modified)

Atty. Docket N .

Serial No.

UTSC:484USC1/TMB

09/943,984

List of Patents and Publications for Applicant's

Applicants

Mien-Chie Hung and Naoto T. Ueno

## INFORMATION DISCLOSURE STATEMENT

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Filing Date:

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See Page 1Foreign Patent Documents  
See Page 1Other Art  
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## U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date if App.
	A1	5,643,567	7/01/97	Hung, <i>et al.</i>			
	A2	5,641,484	6/24/97	Hung <i>et al.</i>	424	93.2	
	A3	4,394,448	7/19/83	Szoka, Jr. <i>et al.</i>	435	172	
	A4	5,776,743	7/7/98	Frisch			
	A5	5,651,964	7/9/97	Hung <i>et al.</i>	424	93.2	
	A6	5,814,315	9/29/98	Hung <i>et al.</i>	424	93.2	
	A7	6,271,207	8/7/01	Cristiano <i>et al.</i>	514	44	

## Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B1	WO 95/16051	06-15-95	PCT			
	B2	WO 95/13813 A	05/26/95	PCT			
	B3	WO 94/21115	09/29/94	PCT			
	B4	WO 93/03769	03/04/93	PCT			
	B5	WO 92/10573 A	06/25/92	PCT			
	B6	WO 90/15595	12/27/90	PCT			
	B7	WO 90/08759 A	08/09/90	PCT			

## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C1	Akiyama <i>et al.</i> , "Genistein, a Specific Inhibitor of Tyrosine-Specific Protein Kinases," <i>J. Biol. Chem.</i> , 262(12):5592-5595, 1987.

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## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C2	Bacus <i>et al.</i> , Differentiation of cultured human breast cancer cells (AU-565) and MCF-7) associated with loss of cell surface <i>HER-2/neu</i> antigen. <i>Mol. Carcinog.</i> , 3:350-362, 1990.
	C3	Bacus, <i>et al.</i> , Tumor-inhibitory monoclonal antibodies to the <i>HER-2/neu</i> receptor induce differentiation of human breast cancer cells. <i>Cancer Res.</i> 52: 2580-2589, 1992.
	C4	Bargmann & Weinberg, "Increased Tyrosine Kinase Activity Associated with the Protein Encoded by the Activated <i>neu</i> Oncogene," <i>Proc. Natl. Acad. Sci. USA</i> , 85:5394-5398, 1988.
	C5	Bargmann <i>et al.</i> , "Multiple Independent Activations of the <i>neu</i> Oncogene by a Point Mutation Altering the Transmembrane Domain of p185," <i>Cell</i> , 45:649-657, 1986.
	C6	Bargmann <i>et al.</i> , "The <i>neu</i> Oncogene Encodes an Epidermal Growth Factor Receptor-Related Protein," <i>Nature</i> , 319:226-230, 1986.
	C7	Berk and Sharp, "Structure of the Adenovirus 2 Early mRNAs," <i>Cell</i> , 14:695-711, 1978.
	C8	Berk, "Adenovirus Promoters and E1A Transactivation," <i>Ann. Rev. Genet.</i> , 20:45-79, 1986.
	C9	Bishop JM "The molecular genetics of cancer," <i>Science</i> , 235 (4786), p305-11, 1987.
	C10	Brader <i>et al.</i> , "Adenovirus E1A Expression Enhances the Sensitivity of an Ovarian Cancer Line to Multiple Cytotoxic Agents Through an Apoptotic Mechanisms," Proceedings of the American Association for Cancer Research, 37:30, 1996. (abstract)
	C11	Brunet <i>et al.</i> , "Concentration Dependence of Transcriptional Transactivation in Inducible E1A-Containing Human Cells," <i>Mol. Cell. Bio.</i> , 8(11):4799-4807 (1988).
	C12	Buchman <i>et al.</i> , Appendix A: The SV40 Nucleotide Sequence, <i>DNA Tumor Viruses</i> , 799-813.
	C13	Chan <i>et al.</i> , "Selective inhibition of the growth of <i>ras</i> -transformed human bronchial epithelial cells by emodin, a protein-tyrosine inhibitor," <i>Biochem. Biophys. Res. Commun.</i> , 193:1152-1158, 1993.
	C14	Chang, <i>et al.</i> , "Paclitaxel by 3-hour infusion followed by 96-hour infusion on failure in patients with refractory malignant disease," <i>Seminars in Oncology</i> , 22(3, Supp.6):124-127, 1995.

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See Page 1

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## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C15	Chevalier, Fumoleau, Kerbrat, Dieras, Roche, Krakowski, Azli, Bayssas, Lentz, Van Glabbeke, "Decetaxel is a major cytotoxic drug for the treatment of advanced breast cancer: a phase II trial of the Clinical Screening Cooperative Group of the European Organization for Research and Treatment of Cancer," <i>J Clin. Oncol.</i> , 13:314-322, 1995.
	C16	Coussens <i>et al.</i> , "Tyrosine Kinase Receptor with Extensive Homology to EGF Receptor Shares Chromosomal Location with <i>neu</i> Oncogene," <i>Science</i> , 230:1132-1139, 1985.
	C17	Douglas <i>et al.</i> , "Modulation of transformation of primary epithelial cells by the second exon of the Ad55 E1A12S gene," <i>Oncogene</i> , 6:2093-2103, 1991.
	C18	Downward <i>et al.</i> , "Close Similarity of Epidermal Growth Factor Receptor and <i>v-erb-B</i> Oncogene Protein Sequences," <i>Nature</i> , 307:521-527, 1984.
	C19	Egan <i>et al.</i> , "Transformation by Oncogenes Encoding Protein Kinases Induces the Metastatic Phenotype," <i>Science</i> , 238:202-205, 1987.
	C20	Felgner <i>et al.</i> , "Gene Therapeutics: The Direct Delivery of Purified Genes <i>in vivo</i> and Their Application as Drugs, Without the Use of Retroviruses, Is Discussed," <i>Nature</i> , 349:351-352 (1991).
	C21	Felgner, P.L., and Ringold, G.M., Cationic liposome-mediated transfection, <i>Nature</i> , 337:387-388, 1989.
	C22	Figge <i>et al.</i> , "Prediction of Similar Transforming Regions in Simian Virus 40 Large T, Adenovirus E1A, and <i>myc</i> Oncoproteins," <i>Journal of Virology</i> , 62:(5)1814-1818, 1988.
	C23	Freedman and Shin, "Use of Nude Mice for Studies on the Tumorigenicity of Animal Cells," <i>The Nude Mouse in Experimental and Clinical Research</i> , 1978.
	C24	Friche <i>et al.</i> , "Effect of anthracycline analogs on photolabelling of p-glycoprotein by [125I]iodomycin and [3H]azidopine: relation to lipophilicity and inhibition of daunorubicin transport in multidrug resistant cells," <i>Br. J. Cancer</i> , 67(2):226-231, 1993.
	C25	Frisch <i>et al.</i> , "Adenovirus E1A Represses Protease Expression and Inhibits Metastasis of Human Tumor Cells," <i>Oncogene</i> , 5:75-83 (1990).
	C26	Fung <i>et al.</i> , "Activation of the Cellular Oncogene <i>c-erbB</i> by LTR Insertion: Molecular Basis for Induction of Erythroblastosis by Avian Leukosis Virus," <i>Cell</i> , 33:357-368, 1983.

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Exam. Init.	Ref. Des.	Citation
	C27	Gazit <i>et al.</i> , "Chemo-adoptive immunotherapy of nude mice implanted with human colorectal carcinoma and melanoma cell lines," <i>Cancer Immunology Immunotherapy</i> , 35:135-144, 1992.
	C28	Giovanella, Stehlin, Shepard, Williams, "Correlation between response to chemotherapy of human tumors in patients and in nude mice," <i>Cancer</i> , 52:1146-1152, 1982.
	C29	Goo, X., and Huang, L., A Novel Cationic Liposome Reagent for Efficient Transfection of Mammalian Cells, <i>Biochemical and Biophysical Research Communication</i> , 179:(1)280-285, 1991.
	C30	Haley <i>et al.</i> , "Transformation Properties of Type 5 Adenovirus Mutants that Differentially Express the E1A Gene Products," <i>Proc. Natl. Acad. Sci. USA</i> , 81:5734-5738, 1984.
	C31	Harlow <i>et al.</i> , "Monoclonal Antibodies Specific for Adenovirus Early Region 1A Proteins: Extensive Heterogeneity in Early Region 1A Products," <i>J. of Virology</i> , 55(3):533-546 (1985).
	C32	Hearing <i>et al.</i> , "Sequence-Independent Autoregulation of the Adenovirus Type 5 E1A Transcription Unit," <i>Mol. Cell. Bio.</i> , 5(11):3214-3221 (1985).
	C33	Houweling <i>et al.</i> , "Partial Transformation of Primary Rat Cells by the Leftmost 4.5% Fragment of Adenovirus 5 DNA," <i>J. Virology</i> , 105:537-550, 1980.
	C34	Hudziak <i>et al.</i> , "Amplified Expression of the HER2/ERBB2 Oncogene Induces Resistance to Tumor Necrosis Factor $\alpha$ in NIH 3T3 Cells," <i>Proc. Natl. Acad. Sci. USA</i> , 85:5102-5106, 1988.
	C35	Hudziak <i>et al.</i> , "Increased expression of the putative growth factor p185 <i>HER2</i> causes transformation and tumorigenesis of NIH 3T3 cells," <i>Proc. Natl. Acad. Sci. USA</i> , 84:7159-7163, 1987.
	C36	Hung <i>et al.</i> , "Amplification of the proto- <i>neu</i> oncogene facilitates oncogenic activation by a single point mutation," <i>Proc. Natl. Acad. Sci. USA</i> , 86:2545-2548, 1989.
	C37	Hung <i>et al.</i> , "Molecular cloning of the <i>neu</i> gene: absence of gross structural alteration in oncogenic alleles," <i>Proc. Natl. Acad. Sci. USA</i> , 83:261-264, 1986.
	C38	Hung, "The <i>neu</i> Proto-Oncogene and Breast Cancer," <i>Cancer Bull.</i> , 40:300-303, 1988.
	C39	Hung, <i>et al.</i> , "Transcriptional Repression of the HER-2/ <i>neu</i> Protooncogene by Transforming Oncogenes from DNA Tumor Virus," Proceedings of the American Association for Cancer Research, Washington, DC, 31:13, Abstract No. 74.

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	C40	Jayasuriya <i>et al.</i> , "Emodin, a protein tyrosine kinase inhibitor from <i>Polygonum cuspidatum</i> ," <i>J. Nat. Prod.</i> , 55:696-698, 1992.
	C41	Jinsart <i>et al.</i> , "Inhibition of Myosin Light Chain Kinase, cAMP-Dependent Protein Kinase, Protein Kinase C and of Plant CA-Dependent Protein Kinase by Anthraquinones," <i>Biological Chemistry</i> , 373:903-910, 1992.
	C42	Kalderon, D., and Smith, A.E., "In Vitro Mutagenesis of a Putative DNA Binding Domain of SV40 Large-T," <i>Virology</i> , 139:109-137, 1984.
	C43	Katsumata <i>et al.</i> , "Prevention of breast tumor development <i>in vivo</i> by down-regulation of the p185 <sup>neu</sup> receptor" <i>Nature Med.</i> , 1: 644-648, 1995
	C44	Kelner, McMorris, Estes, Starr, Samson, Varki, Taetle, "Nonresponsiveness of the metastatic human lung carcinoma MV522 xenograft to conventional anticancer agents," <i>Anticancer Res.</i> , 15:867-872, 1995.
	C45	Kern <i>et al.</i> , "p185 <sup>neu</sup> expression in human lung adenocarcinomas predicts shortened survival," <i>Cancer Res.</i> , 50:5184-5191, 1990.
	C46	Kiyokawa N ; Yan DH; Brown ME; Hung MC "Cell cycle-dependent regulation of p185 <sup>neu</sup> : a relationship between disruption of this regulation and transformation." <i>Proc Natl Acad Sci USA</i> , 92 (4) p1092-61995.
	C47	Kraus <i>et al.</i> , "Overexpression of the EGF Receptor-Related Proto-Oncogene <i>erbB-2</i> in Human Mammary Tumor Cell Lines by Different Molecular Mechanisms," <i>EMBO J.</i> , 6(3):605-610, 1987.
	C48	Kupchan and Karim, "Tumor Inhibitors 114. Aloe Emodin: Antileukemia Principle Isolated from <i>Rhamnus frangula</i> ," <i>L. Lloydia</i> , 39:223-224, 1976.
	C49	Land <i>et al.</i> , "Cellular Oncogenes and Multistep Carcinogenesis," <i>Science</i> , 222:771-776, 1983.
	C50	Lee, Bruckner, Szrajer, Brenne, Schindelheim, Andretti, "Taxol inhibits growth of Mesothelioma xenografts," <i>Anticancer Res.</i> , 15:693-696, 1995.
	C51	Lehvaslaiho <i>et al.</i> , "A chimeric EGF-R- <i>neu</i> proto-oncogene allows EGF to regulate <i>neu</i> tyrosine kinase and cell transformation," <i>EMBO Journal</i> , 8:(1)159-166, 1989.

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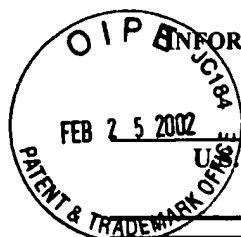
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	C52	Leibiger <i>et al.</i> , "Expression of exogenous DNA in rat liver cells after liposome-mediated transfection <i>in vivo</i> ," <i>Biochemical and Biophysical Research Communications</i> , 174:(3)1223-1231, 1991.
	C53	Li <i>et al.</i> , "Method of Identifying Inhibitors of Oncogenic Transformation: Selective Inhibition of Cell Growth in Serum-Free Medium," <i>Oncogene</i> , 8:1731-1735, 1993.
	C54	Lichtenstein <i>et al.</i> , "Resistance of Human Ovarian Cancer Cells to Tumor Necrosis Factor and Lymphokine-Activated Killer Cells: Correlation with Expression of HER2/ <i>neu</i> Oncogenes," <i>Cancer Research</i> , 50:7364-7370, 1990.
	C55	Liu <i>et al.</i> , "Evidence for Involvement of Tyrosine Phosphorylation in Taxol-Induced Apoptosis in a Human Ovarian Tumor Cell Line," <i>Biochem. Pharmacol.</i> , 48(6):1265-1272, 1994.
	C56	Lupu <i>et al.</i> , "Direct Interaction of a Ligand for the <i>erbB2</i> Oncogene Product with the EGF Receptor and p185 <sup>erbB2</sup> ," <i>Science</i> , 249:1552-1554, 1990.
	C57	Matin and Hung, "Negative Regulation of the <i>Neu</i> Promoter by the SV40 Large T Antigen," <i>Cell Growth &amp; Differentiation</i> , 4:1051-1056, 1993.
	C58	Matin, "Regulation of <i>neu</i> gene expression by the simian virus 40 large T antigen and tumor suppressors Rb and p53," <i>Diss. Abstr. Int. B</i> , 54(5):2365, 1993.
	C59	Minna <i>et al.</i> , "Cancer of the lung," In: Devita, V.T., Hellmen, S., Rosenberg, S.A. (eds.) <i>In: Principles and Practice of Oncology</i> , Philadelphia: J.B. Lippincott, pp591-705, 1989.
	C60	Montell <i>et al.</i> , "Complete Transformation by Adenovirus 2 Requires Both E1A Proteins," <i>Cell</i> , 36:951-961, 1984.
	C61	Moran <i>et al.</i> , "Multiple Functional Domains in the Adenovirus E1A Gene," <i>Cell</i> , 48:177-178 (1987).
	C62	Müller <i>et al.</i> , "Differential Expression of Cellular Oncogenes During Pre- and Postnatal Development of the Mouse," <i>Nature</i> , 299:640-644, 1982.
	C63	Muller <i>et al.</i> , "Single-Step Induction of mammary adenocarcinoma in transgenic mice bearing the activated <i>c-neu</i> oncogene," <i>Cell</i> , 54:105-115, 1988.
	C64	Muthuswamy <i>et al.</i> , "Mammary tumors expressing the <i>neu</i> proto-oncogene possess elevated <i>c-src</i> tyrosine kinase activity," <i>Mol. Cell. Biol.</i> , 14:735-743, 1994.

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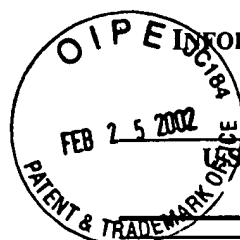
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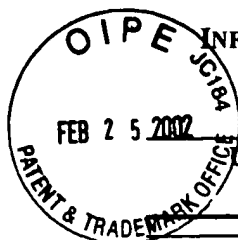
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See Page 1

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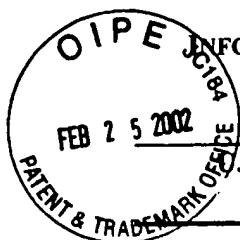
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